

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ACTELION PHARMACEUTICALS LTD,

Plaintiff,

v.

ZYDUS PHARMACEUTICALS (USA)
INC., *et al.*,

Defendants.

Civil Action No. 18-1397 (FLW)(LHG)

**PRETRIAL
SCHEDULING ORDER**

THIS MATTER having come before the Court for an Initial Conference pursuant to Fed. R. Civ. P. 16; William Baton, Esq., of Saul Ewing Arnstein & Lehr LLP, and Preston Ratliff, II, Esq., Alison Mulry, Esq., and Mark Sperling, Esq., of Paul Hastings LLP, appearing on behalf of Plaintiff Actelion; Christy Saveriano, Esq., of Hill Wallack LLP, and Michael Gaertner, Esq., and James Peterka, Esq., of Locke Lord LLP appearing on behalf of Defendant Zydus; Rebekah Conroy, Esq., of Stone Conroy LLC, and Ronald Daignault, Esq., of Goldberg Segalla LLP, appearing on behalf of Defendant Amneal Pharmaceuticals LLC; the Court having set certain deadlines during the conference with the participation of counsel; and for good cause shown,

IT IS on this **23rd** day of **May, 2018**,

ORDERED that the following schedule shall apply to this matter which arises under 21 U.S.C. § 355 (commonly referred to as “the Hatch-Waxman Act”) and involves a Paragraph IV certification:

1. By no later than **May 8, 2018**, the parties shall exchange Initial Disclosures under Fed. R. Civ. P. 26.
2. By **May 8, 2018**, in accordance with L. Pat. R. 3.6(b), Plaintiff shall serve on Defendants a “Disclosure of Asserted Claims” that lists each claim of each patent that is allegedly infringed by Defendants, including for each claim the applicable statutory subsections of 35 U.S.C. § 271 asserted.
3. By **May 29, 2018**, the parties are to submit a proposed Discovery Confidentiality Order pursuant to L. Pat. R. 2.2. (Please note that this deadline differs from the one provided at the Initial Conference and reflects the Court’s grant of the parties’ joint letter request submitted May 15, 2018 [Docket Entry No. 27] seeking a two-week extension.)
4. By **May 31, 2018**, in accordance with L. Pat. R. 3.6(c), Defendants shall provide to Plaintiff the written basis for its “Invalidity Contentions,” for any patents referred to in Defendants’ Paragraph IV Certification, which shall contain all disclosures required by Paragraph 5 below. Any “Invalidity Contentions,” disclosed under L. Pat. R. 3.6(c) shall be accompanied by the production of documents required under Paragraph 6 below.

5. As provided in L. Pat. R. 3.3, any “Invalidity Contentions” shall contain the following information:
 1. The identity of each item of prior art that allegedly anticipates each asserted claim or renders it obvious. Each prior art patent shall be identified by its number, country of origin, and date of issue. Each prior art publication shall be identified by its title, date of publication, and where feasible, author and publisher. Prior art under 35 U.S.C. § 102(b) shall be identified by specifying the item offered for sale or publically used or known, the date of the offer or use took place or the information became known, and the identity of the person or entity which made the use or which made and received the offer, or the person or entity which made the information known or to whom it was made known. Prior art under 35 U.S.C. § 102(f) shall be identified by providing the name of the person(s) from whom and the circumstances under which the invention or any part of it was derived. Prior art under 35 U.S.C. § 102(g) shall be identified by providing the identities of the person(s) or entities involved in and the circumstances surrounding the making of the invention before the patent applicant(s);
 - a. Whether each item of prior art anticipates each asserted claim or renders it obvious. If obviousness is alleged, an explanation of why the prior art renders the asserted claim obvious, including an identification of any combinations of prior art showing obviousness;
 2. Other than for design patents, a chart identifying where specifically in each alleged item of prior art each limitation of each asserted claim is found, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in each item of prior art that performs the claimed function; and
 3. Any grounds of invalidity based on 35 U.S.C. § 101, indefiniteness under 35 U.S.C. § 112(2) or enablement or written description under 35 U.S.C. § 112(1) of any of the asserted claims.
4. As provided in L. Pat. R. 3.4, Defendants shall produce or make available for inspection and copying:
 5. A copy or sample of the prior art identified pursuant to L. Pat. R. 3.3(a) which does not appear in the file history of the patent(s) at issue. To the extent any such item is not in English, an English translation of the portion(s) relied upon shall be produced; and
 6. Defendants shall also produce any other document or thing on which it intends to rely in support of its assertion.
7. By **May 31, 2018**, in accordance with L. Pat. R. 3.6(e), Defendants shall provide to Plaintiff the written basis for its “Non-Infringement Contentions,” for any patents referred to in the opposing party’s Paragraph IV Certification which shall include a claim chart identifying each claim at issue in the case and each limitation of each claim at issue. The claim chart shall specifically identify for each claim which claim limitation(s) is/(are) literally absent from Defendants’ allegedly infringing Abbreviated New Drug Application or New Drug Application. Any “Non-Infringement Contention” disclosed under L. Pat. R. 3.6(e), shall

be accompanied by the production of any document or thing that each party who is an ANDA filer intends to rely on in defense against any infringement contentions by each party asserting patent infringement.

8. Any motion to amend the pleadings or join new parties must be brought with leave of Court and filed no later than **July 2, 2018**, and made returnable by **August 6, 2018**.
9. By **July 12, 2018**, in accordance with 3.6(g), Plaintiff will provide Defendants with a “Disclosure of Infringement Contentions,” for all patents referred to in Defendants’ Paragraph IV Certification, which shall contain all disclosures required by Paragraph 9 below. The infringement contentions shall be limited to the claims identified in L. Pat. R. 3.6(b), “Disclosure of Asserted Claims.” Any “Disclosure of Infringement Contentions” disclosed under L. Pat. R. 3.6(g), shall be accompanied by the production of documents under L. Pat. R. 3.2, as set forth in Paragraph 10 below.
10. As provided in L. Pat. R. 3.1, the party asserting patent infringement shall serve on all parties a “Disclosure of Asserted Claims and Infringement Contentions.” Separately for each opposing party, the “Disclosure of Asserted Claims and Infringement Contentions” shall contain the following information:
 11. Each claim of each patent in suit that is allegedly infringed by each opposing party including for each claim the applicable statutory subsection of 35 U.S.C. § 271 asserted;
 12. Separately for each asserted claim, each accused apparatus, product, device, process, method, act or other instrumentality (“Accused Instrumentality”) of each opposing party of which the party is aware. This identification shall be as specific as possible. Each product device, and apparatus shall be identified by name or model number, if known. Each method or process shall be identified by name, if known, or by any product, device, or apparatus which, when used, allegedly results in the practice of the claimed method or process;
 13. Other than for design patents, a chart identifying specifically where each limitation of each asserted claim is found within each Accused Instrumentality, including for each limitation that such party contends is governed by 35 U.S.C. § 112(6), the identity of the structure(s), act(s), or material(s) in the Accused Instrumentality that performs the claimed function;
 14. For each claim which is alleged to have been indirectly infringed, an identification, of any direct infringement and a description of the acts of the alleged indirect infringer that contribute to or are inducing that direct infringement. Insofar as alleged direct infringement is based on joint acts of multiple parties, the role of each such party in the direct infringement must be described;
 15. Other than for design patents, whether each limitation of each asserted claim is alleged to be literally present or present under the doctrine of equivalents in the Accused Instrumentality;
 16. For any patent that claims priority to an earlier application, the priority date to which each asserted claim allegedly is entitled;

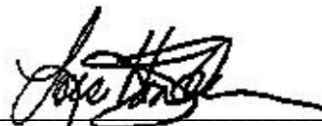
17. If a party asserting patent infringement wishes to preserve the right to rely, for any purpose, on the assertion that its own apparatus, product, device, process, method, act or other instrumentality practices the claimed invention, the party shall identify, separately for each asserted claim, each such apparatus, product, device, process, method, act, or other instrumentality that incorporates or reflects that particular claim; and
18. If a party asserting patent infringement alleges willful infringement, the basis for such allegation.
19. As provided in L. Pat. R. 3.2, with the “Disclosure of Asserted Claims and Infringement Contentions,” the party asserting patent infringement shall produce to each opposing party or make available for inspection and copying:
 20. Documents (e.g., contracts, purchase orders, invoices, advertisements, marketing materials, offer letters, beta site testing agreements, and third party or joint development agreements) sufficient to evidence each discussion with, disclosure to, or other manner of providing to a third party, or sale of or offer to sell, or any public use of, the claimed invention prior to the date of application for the patent in suit. A party’s production of documents as required herein shall not constitute an admission that such document evidences or is prior art under 35 U.S.C. § 102;
 21. All documents evidencing the conception, reduction to practice, design, and development of each claimed invention, which were created on or before the date of application for the patent in suit or the priority date identified pursuant to L. Pat. R. 3.1(f), whichever is earlier;
 22. A copy of the file history for each patent in suit (or so much thereof as in the possession of the party asserting patent infringement);
 23. All documents evidencing ownership of the patent rights by the party asserting patent infringement;
 24. If a party identifies instrumentalities pursuant to L. Pat. R. 3.1(g), documents sufficient to show the operation of any aspects or elements of such instrumentalities the party asserting patent infringement relies upon as embodying any asserted claims; and
 25. All documents or things that a party asserting patent infringement intends to rely on in support of any of its infringement contentions under the Local Patent Rules.
 26. With respect to each of the above documents productions, the producing party shall separately identify by production number which documents correspond to each category.
27. By **July 12, 2018**, in accordance with L. Pat. R. 3.6(i), Plaintiff shall serve on Defendants its “Responses to Invalidity Contentions” as required under L. Pat. R. 3.4A as set forth in the following paragraph.
28. Plaintiff’s “Responses to Invalidity Contentions” under L. Pat. R. 3.4A shall include the following:

29. For each item of asserted prior art, the identification of each limitation of each asserted claim that the party believes is absent from the prior art, except for design patents, where the party shall supply and explanation why the prior art does not anticipate the claim;
30. If obviousness is alleged, an explanation of why the prior art does not render the asserted claim obvious;
31. The party's responses shall follow the order of the invalidity chart required under L. Pat. R. 3.3(c), and shall set forth the party's agreement or disagreement with each allegation therein and the written basis thereof; and
32. The production or the making available for inspection and copying of any document or thing that the party intends to rely on in support of its Responses therein.
33. By **July 26, 2018**, in accordance with L. Pat. R. 4.1(a), the parties shall serve on each other a list of claim terms which that party contends should be construed by the Court, and identify any claim term which that party contends should be governed by 35 U.S.C. § 112(6).
34. In accordance with L. Pat. R. 4.1(b), the parties shall meet and confer for the purposes of limiting the terms in dispute by narrowing or resolving differences and facilitating the ultimate preparation of a Joint Claim and Pre-hearing Statement.
35. By **August 16, 2018**, in accordance with L. Pat. R. 4.2, the parties shall simultaneously exchange preliminary proposed constructions of each term identified by any party for claim construction. Each such "Preliminary Claim Construction" shall also, for each term which any party contends is governed by 35 U.S.C. § 112(6), identify the structure(s), act(s), or material(s) corresponding to that term's function.
36. At the same time the parties exchange their respective "Preliminary Claim Constructions," each party shall also identify all intrinsic evidence, all references from the specification or prosecution history that support its preliminary proposed construction and designate any supporting extrinsic evidence including, without limitation, dictionary definitions, citations to learned treatises and prior art and testimony of all witnesses including expert witnesses. Extrinsic evidence shall be identified by production number or by producing a copy if not previously produced. With respect to all witnesses including experts, the identifying party shall also provide a description of the substance of that witness' proposed testimony that includes a listing of any opinions to be rendered in connection with claim construction.
37. By **August 30, 2018**, in accordance with L. Pat. R. 4.2(c), the parties shall exchange an identification of all intrinsic evidence and extrinsic evidence that each party intends to rely upon to oppose any other party's proposed construction, including without limitation, the evidence referenced in Paragraph 15(a) above.
38. In accordance with L. Pat. R. 4.2(d), the parties shall meet and confer for the purposes of narrowing the issues and finalizing preparation of a Joint Claim Construction and Pre-hearing Statement.

39. By **September 13, 2018**, in accordance with L. Pat. R. 4.3, the parties shall complete and file a Joint Claim Construction and Pre-hearing Statement, which shall contain the following information:
- 40. The construction of those terms on which the parties agree;
 - 41. Each party's proposed construction of each disputed term, together with an identification of all references from the intrinsic evidence that support that construction, and an identification of any extrinsic evidence known to the party on which it intends to rely either to support its proposed construction or to oppose any other party's proposed construction, including, but not limited to, as permitted by law, dictionary definitions, citations to learned treatises and prior art, and testimony of all witnesses including experts;
 - 42. An identification of the terms whose construction will be most significant to the resolution of the case. The parties shall also identify any term whose construction will be case or claim dispositive or substantially conducive to promoting settlement, and the reasons therefor;
 - 43. The anticipated length of time necessary for the Claim Construction Hearing; and
 - 44. Whether any party proposes to call one or more witnesses at the Claim Construction Hearing, the identity of each such witness, and for each witness, a summary of his or her testimony including, for any expert, each opinion to be offered related to claim construction.
 - 45. Any evidence that is not identified under L. Pat. R. 4.2(a) through 4.2(c) inclusive shall not be included in the Joint Claim Construction and Pre-hearing Statement.
46. By **October 15, 2018**, in accordance with L. Pat. R. 4.4, the parties shall complete all discovery relating to claim construction, including any depositions with respect to claim construction of any witnesses, other than experts, identified in the Preliminary Claim Construction statement (L. Pat. R. 4.2) or Joint Claim Construction and Pre-hearing Statement (L. Pat. R. 4.3).
47. By **October 25, 2018**, in accordance with L. Pat. R. 4.5(a), the parties shall contemporaneously file and serve their opening *Markman* briefs and any evidence supporting claim construction, including experts' certifications or declarations.
48. By **November 26, 2018**, in accordance with L. Pat. R. 4.5(b), the parties shall complete discovery from any expert submitting a claim construction certification or declaration.
49. By **December 18, 2018**, in accordance with L. Pat. R. 4.5(c), the parties shall contemporaneously file and serve responsive *Markman* briefs and any evidence supporting claim construction, including any responsive experts' certifications or declarations.
50. By **December 18, 2018**, the parties shall file a joint letter requesting a date for a claim construction hearing.

51. Within **30 days** of the issuance of a claim construction order, Defendants are to disclose whether it will assert an advice of counsel defense, and is to produce documents related to such a defense.
52. By **May 30, 2019**, the parties are to substantially complete document production.
53. Fact discovery is to remain open through **August 29, 2019**. No discovery is to be issued or engaged in beyond that date, except upon application and for good cause shown
54. The parties shall serve any affirmative expert reports no later than **October 15, 2019**.
55. The parties shall serve any rebuttal expert reports no later than **November 30, 2019**.
56. The parties shall serve any reply expert reports no later than **December 30, 2019**.
57. The parties will complete all expert discovery by **January 30, 2019**.
58. Any dispositive motions may be filed by no later than **March 10, 2020**, and made returnable **April 13, 2020**. Counsel are to notify the chambers of the undersigned within five days of a decision on any dispositive motion if the decision does not resolve all issues in the case.
59. Counsel will confer in an attempt to resolve any discovery or case management disputes before making such dispute the subject of an application to the Court. Any such dispute shall be brought to the Court's attention by letter, no more than five pages in total, preferably emailed to chambers at lhg_orders@njd.uscourts.gov, setting forth the nature of the dispute and any efforts to resolve it. Any response shall be similarly limited to five pages in total and shall be submitted within forty-eight hours of the initial letter. **No discovery motion or motion for leave to amend will be entertained absent leave of Court and counsel's full compliance with L. Civ. R. 37.1(a)(1); see also L. Civ. R. 16.1(f).**
60. A telephone status conference will be held before the undersigned on **September 27, 2018 at 11:00 a.m.** Plaintiff is to initiate the call to chambers at that time.
61. Appropriate markers shall be affixed to the exhibits at or prior to the time they are shown to opposing counsel at the meeting of counsel referred to above, and each marker will bear the number of the exhibit to which it is affixed.
62. An in-person Final Pretrial Conference will be held before the undersigned on **August 10, 2020 at 10:00 a.m.** Counsel are to be prepared to discuss settlement of the case at the conference. A client representative with full settlement authority is to be immediately available by telephone. By no later than **August 5, 2020**, the parties shall submit a proposed Final Pretrial Order in MS WORD format, with one courtesy hardcopy forwarded to chambers.
63. On **October 5, 2020**, trial as to all claims will commence before the Honorable Freda L. Wolfson, U.S.D.J., unless otherwise ordered by the Court. Trial is tentatively scheduled for 2 weeks.

64. All dates set forth herein are established with the assistance and knowledge of the parties, there will be no extensions except for good cause shown and by leave of Court, even with consent of all parties.
65. The Court may, from time to time, schedule conferences as may be required, either on its own motion or at the request of counsel.
66. Failure to appear at subsequent conferences, or to comply with any of the terms of this Order, may result in sanctions.
67. The parties are advised that the Court has various audio/visual and evidence presentation equipment available for use at trial at no cost to the parties. This equipment includes an evidence presentation system, which consists of a document camera and a projector. The projector may be used to display images which originate from a variety of sources, including television, VCR and personal computer. The document camera may be used to display documents, photographs, charts, transparencies and small objects. For further information, please contact the Courtroom Deputy, Ivannya Jimenez.
68. A hard copy of any letter memoranda that is emailed to chambers should not be mailed to chambers unless specifically advised otherwise. All proposed orders and letter memoranda emailed to chambers should be in MS WORD format and emailed to: lhg_orders@njd.uscourts.gov. Any filings with the Clerk of the Court should be in PDF format.
69. Counsel are invited to use the George H. Barlow Attorney Conference Room located on the third floor of the Courthouse Annex. The room is equipped with telephones, laptop and printer access, copier, and facsimile.



LOIS H. GOODMAN
United States Magistrate Judge